



Massachusetts Department of Public Health Patient Safety Update Retained Foreign Objects

Retained Foreign Objects Background

This publication is being distributed to all Massachusetts hospitals required to report Serious Reportable Events (SREs) to the Department of Public Health (DPH) as mandated by Chapter 305 of the Acts of 2008. The publication is intended to provide a summary of information and current best practices on retained foreign objects (RFO), one of 28 SREs reported to DPH and defined by the National Quality Forum (NQF).

This information is presented as part of a collaboration between the Quality and Patient Safety Division (QPSD) (formerly known as the Patient Care Assessment Division) of the Board of Registration in Medicine, the Bureau of Health Care Safety and Quality (BHCSQ) within DPH and the Betsy Lehman Center for Patient Safety and Medical Error Reduction.

As documented in DPH's April 2009 and April 2010 reports, *Serious Reportable Events in Massachusetts Acute Care Hospitals*, acute care hospitals reported 32 RFOs in calendar year 2008 and 42 RFOs in calendar year 2009.

Massachusetts numbers are comparable to those of other states required to report

SREs. Minnesota reported 38 cases of RFOs in the reporting period of October 2008 to October 2009.¹ New Jersey's reports nearly doubled in one year, from 14 in 2007 to 27 in 2008.²

In the context of SRE reporting for RFOs in a patient after surgery or other procedure, surgery is defined as an invasive operative procedure in which skin or tissue are incised or an instrument is introduced through a natural body orifice. Surgeries include a range of procedures from minimally invasive (such as some biopsies) to extensive multi-organ transplantation. A RFO after surgery is the occurrence of unintended retention of objects at any point after the surgery ends.³ Examples include retention of a sponge, cannula tip, or guide wire.

Mortality rates resulting from unintended retention of foreign objects in surgical patients are as high as 35%, and objects are left in 1,500 people each year in the United States.⁴ In a 2003 case-control study of 54 patients involving RFOs, 69% of the objects were sponges and 31% were instruments. More than half (54%) of the foreign bodies were left in the

abdomen or pelvis, 29% in the vagina, 7% in the thorax and 10% elsewhere.⁵ Massachusetts data from 2008 deviates from this study; of the 32 RFOs reported that year, less than one third were sponges, and the rest were instruments, such as wires, tips, and needles. Of the Massachusetts RFOs reported, 34% involved the abdomen or pelvis. Twenty-five percent involved chest procedures, 25% involved skeletal operations, and the remaining 16% were elsewhere.

Since June 2008, Massachusetts, as a health insurance purchaser, has not reimbursed hospitals for costs associated with any occurrence on the NQF list.⁶ In October 2008, the Centers for Medicare and Medicaid Services (CMS) stopped reimbursing for foreign objects retained after surgery.⁷ Effective June 15, 2009, hospitals in Massachusetts are prohibited from seeking reimbursement for services provided as a result of the occurrence of any of the 28 NQF defined SRE-related services.⁸

Case Study Section

The following section provides several cases where retained foreign objects were reported to DPH. They demonstrate two examples of what has been reported and the initial changes made as a result of the hospitals' analyses of the events.

Case 1:

A patient underwent cervical spinal surgery utilizing a retractor system that included screws. During post-operative care, the patient experienced discomfort at the surgical site. An x-ray showed a 2 1/2 inch screw remained in the patient. The screw was surgically removed.

Response:

Prior to this incident, screws included as part of retractor systems had not been separately identified in the instrument count. The facility revised the instrument count to include the screws and provided an in-service to staff instructing them of this change.

Case 2

A patient had a peripherally inserted central catheter. Several days after the catheter placement, a CAT scan revealed that a guide wire remained in the patient. The guide wire was removed by Interventional Radiology.

Response:

The root cause analysis found that the anesthesiologist encountered bleeding when the guide wire for catheter placement was removed. He removed the catheter and opened a new catheter kit and inserted the second catheter. There was again heavy bleeding from the catheter ports when the catheter was in place. The anesthesiologist left the guide wire in place to tamponade the bleeding in one of the ports. After clamping of proximal ports, assessing the patient's vital signs and flushing of the distal port, the anesthesiologist did not see the guide wire. The packaging from the two catheter kits was still on the field.

Noting the guide wire from the first kit, it was mistaken for the guide wire from the second kit.

It was recommended that when a second catheter kit is needed, any material from the first kit should be removed from the

field. Guide wires should not be used for tamponade of bleeding from ports; a clamp on the tubing can be used to stop blood back flow.

Retained Foreign Object Prevention

The Joint Commission, a health care facility accrediting organization, includes RFOs in its list of sentinel events. A sentinel event is any unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.

In 2008, the Joint Commission reported that RFOs were the fourth most frequently reported sentinel event in its data base.⁹

According to the Joint Commission, miscommunication was the number one causal reason identified in all root cause analyses of all sentinel events from 1995 to 2005.¹⁰ With RFOs, the Joint Commission cites the following as higher risk categories for retaining an object: emergency procedures, deviation from planned procedures, abdominal or pelvis procedures, patients with high body mass indices and failure to count or inaccurate counts of all implements used during the procedure.¹¹

The American College of Surgeons has published a [statement](#) on the prevention of RFOs after surgery offering guidance that can be adapted to various practice settings, such as ambulatory surgical centers, doctors' offices and all other areas where operative and invasive procedures are performed.¹²

Surgical procedures take place within a system of perioperative care composed of surgeons, perioperative registered nurses, surgical technologists and anesthesia professionals. These individuals share a common ethical, legal and moral responsibility to promote an optimal patient outcome.

Prevention of foreign object retention requires good communication among perioperative personnel and the consistent application of reliable and standardized processes of care.

The American College of Surgeons recommends to prevent the retention of sponges, sharps, instruments and other designated miscellaneous items include:

- * Maintenance of an optimal OR environment to allow focused performance of operative tasks;
- * Consistent application and adherence to standardized counting procedures;
- * Performance of a methodical wound exploration before closure of the surgical site;
- * Use of X-ray detectable items in the surgical wound; and
- * Employment of X-ray or other technology (e.g., radiofrequency detection, bar coding) as indicated, to ensure there is no unintended item remaining in the operative field.

These measures can be suspended as required in life-threatening situations.

Documentation should include, but not be limited to: results of surgical item

counts, notification of the surgical team members, instruments or items intentionally left as packing, and actions taken if count discrepancies occur.

Surgical facilities must provide resources to ensure that necessary equipment and personnel are available to support these perioperative surgical safety measures.

Policies and procedures for the prevention of RFOs should be developed, reviewed periodically, revised as necessary, and available in the practice setting.

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Both the 2008 and 2009 *Serious Reportable Events in Massachusetts Acute Care Hospitals* reports are available at: <http://www.mass.gov/dph/dhcq> (scroll down to “Serious Reportable Event”).

References

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- ¹ Minnesota Department of Health, “Adverse Health Events in Minnesota, Sixth Annual Report,” January 2010, Accessed May 26, 2010.
<http://www.health.state.mn.us/patientsafety/publications/2010ahe.pdf>
- ² Health Care Quality Assessment, New Jersey Department of Health and Senior Services, “Patient Safety Reporting System, 2008 Summary Report”, March 2010, Accessed May 26, 2010.
http://www.state.nj.us/health/ps/documents/2008_summary_report.pdf
- ³ National Quality Forum, “Serious Reportable Events Update 2006,”
<http://www.qualityforum.org/Topics/Safety.aspx>, Accessed May 26, 2010.
- ⁴ Joint Commission on Accreditation of Health Care Organizations, “Focus on Five, Preventing Retained Foreign Objects, Improving Safety After Surgery,” *Joint Commission Perspectives on Patient Safety*, March 2006, Volume 6, Issue 3.
- ⁵ Gawande, A.A., et al., “Risk factors for retained instruments and sponges after surgery,” *N Engl J Med*, 348:229-235, Jan 16, 2003.
- ⁶ “Patrick Administration Announces Non-Payment Policy for 28 Serious Reportable Events,”
http://www.mass.gov/?pageID=eohhs2pressrelease&L=1&L0=Home&sid=Eeohhs2&b=pressrelease&f=080618_non_payment_policy&csid=Eeohhs2, Accessed May 26, 2010.
- ⁷ Centers for Medicare and Medicaid Services, “Hospital Acquired Condition,”
http://www.cms.hhs.gov/HospitalAcqCond/06_Hospital-Acquired_Conditions.asp, Accessed May 26, 2010.
- ⁸ Department of Public Health, Bureau of Health Care Quality and Safety, “Memorandum to Promulgate Amendments to 105CMR 130.000 (Hospital Licensure) to Implement Provisions of Chapter 305 of the Acts of 2008,” May 26, 2010.
- ⁹ Joint Commission, “Sentinel Event Trends Reported by Year, Updated through 2008.”
<http://www.jointcommission.org/SentinelEvents/Statistics>, Accessed May 26, 2010.
- ¹⁰ Institute for Clinical Systems Improvement, “Prevention of Unintentionally Retained Foreign Objects During Vaginal Deliveries,” *Health Care Protocol*, 2nd Ed. September 2008,
http://www.icsi.org/guidelines_and_more/protocols/_patient_safety_reliability_protocols/retained_foreign_objects_during_vaginal_deliveries/retained_foreign_objects_during_vaginal_deliveries_protocol.html, Accessed May 26, 2010.
- ¹¹ Joint Commission, “Resources, Foreign Objects Retained After Surgery,” January 2009,
<http://www.jcrinc.com/Foreign-Objects-Retained-After-Surgery/>, Accessed May 26, 2010.
- ¹² American College of Surgeons, “Statement on the prevention of retained foreign bodies after surgery,” October 2005, http://www.facs.org/fellows_info/statements/st-51.html, Accessed May 26, 2010.